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NVI 5183.1 PATENT

#### AMENDMENTS TO THE CLAIMS

### **Listing of Claims:**

- 1. (currently amended) A composition for the prevention or control of coccidiosis comprising viable non-attenuated sporulated oocysts that are derived from an oocysts source comprising bacterial contamination and comprise [of] at least one species of protozoa known to cause coccidiosis, wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% 0.4% by weight of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores.
  - 2. (cancelled)
  - 3. (cancelled)
- 4. (currently amended) A composition as set forth in claim 3 1 wherein the composition contains less than about 0,2% by weight of alkali metal dichromate.
- 5. (original) A composition as set forth in claim 4 wherein the composition contains less than about 0.1% by weight of alkali metal dichromate.
- 6. (previously presented) A composition as set forth in claim 1 wherein said composition is substantially free of alkali metal dichromate.

- 7. (original) A composition as set forth in claim 1 wherein said composition contains less than about 0.3% by weight of dichromate ion.
- 8. (original) A composition as set forth in claim 7 wherein said composition contains less than about 0.15% by weight of hexavalent chromium.
- 9. (currently amended) A composition for the prevention or control of coccidiosis comprising viable non-attenuated sporulated occysts that are derived from an occysts source comprising bacterial contamination and comprise [of] at least one species of protozoa known to cause coccidiosis, wherein said composition is sterile and contains at least about 300 occysts per milliliter and less than about 0.002% by weight of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said occysts by tangential flow filtration of an aqueous process medium containing said occysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated occysts cannot enter the pores, but said bacterial contaminants can pass through the pores.
- 10. (currently amended) A composition for the prevention or control of coccidiosis comprising viable non-attenuated sporulated oocysts that are derived from an oocysts source comprising bacterial contamination and comprise [of] at least one species of protozoa known to cause coccidiosis, wherein said composition is sterile and contains less than about 5.0 x 10<sup>-3</sup> µg of alkali metal dichromate per oocyst, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores.

- 11. (original) A composition as set forth in claim 10 wherein said composition is sterile and contains less than about 3.8 x 10<sup>-3</sup> µg of alkali metal dichromate per oocyst.
- 12. (original) composition as set forth in of claim 11 wherein said composition is sterile and contains less than about  $1.3 \times 10^{-3} \mu g$  of alkali metal dichromate per occyst.
- 13. (original) A composition as set forth in of claim 12 wherein said composition is sterile and contains less than about  $6.3 \times 10^{-6} \, \mu g$  of alkali metal dichromate per occyst.
  - 14. (original) A composition as set forth in claim 1, further comprising a diluent.
- 15. (original) A composition as set forth in claim 14, wherein the diluent comprises water.
- 16. (original) A composition as set forth in claim 15, wherein the aqueous diluent comprises 0.5X phosphate buffered saline.
  - 17. (original) A composition as set forth in claim 16 further comprising a buffer.
- 18. (original) A composition as set forth in claim 17, wherein said buffer is selected from the group consisting of phosphate buffer, bicarbonate buffer, citric acid and tris buffers.
- 19. (previously presented) A composition as set forth in claim 17, wherein said buffer controls pH between about 7.0 and about 7.8.
- 20. (original) A composition as set forth in claim 14, further comprising a bactericide.

- 21. (original) A composition as set forth in claim 20, wherein said bactericide is selected from the group consisting of potassium perchlorate, sodium hypochlorite, hydrochlorous acid, sodium hydroxide and antibiotics.
- 22. (original) A composition as set forth in of claim 21, wherein said composition contains from about 0.1 to about 0.75 wt% potassium perchlorate, and/or from about 0.001 to about 0.01 wt% sodium hypochlorite, and/or from about 1 to about 5 ppm hydrochlorous acid, and/or from about 0.5 to about 1.5 mM sodium hydroxide and/or from about 20 to about 30 µg/ml gentamicin, in the final composition.
- 23. (original) A composition as set forth in claim 14, further comprising a composition that ameliorates a decline in post-challenge performance.
- 24. (original) A composition as set forth in claim 23, wherein said composition is selected from the group consisting of Alum, Freund's adjuvant, calcium phosphate, beryllium hydroxide, dimethyl dioctadecyl ammonium bromide, saponins, polyanions, Quil A, inulin, lipopolysaccharide endotoxins, liposomes, lysolecithins, zymosan, propionibacteria, mycobacteria, interleukin-1, interleukin-2, interleukin-4, interleukin-6, interleukin-12, interferon-α, interferon-γ, and granulocyte-colony stimulating factor.
- 25. (original) A composition as set forth in claim 23, wherein said composition is selected from the group consisting of cytokines, growth factors, chemokines, mitogens and adjuvants.
- 26. (original) A composition as set forth in claim 25, wherein said composition comprises *Propionibacterium acnes*.

- 27. (original) A composition as set forth in claim 26, wherein said composition contains at least about 3.0 milligrams (dry weight) of *P. acnes* per milliliter.
- 28. (original) A composition as set forth in claim 26, wherein said composition contains at least about 30 milligrams (dry weight) of *P. acnes* per milliliter.
- 29. (currently amended) A composition as set forth in claim 1 comprising: viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis,
  - a diluent.
  - a buffer, and
  - a bactericide,
- wherein said composition contains about 10,000 oocysts pers milliliter and less than about 0.8% 0.4% weight to volume of alkali metal dichromate.
- 30. (original) A composition as set forth in claim 29, further comprising a composition that ameliorates a decline in post-challenge performance.

Claims 31-112. (cancelled).

113. (currently amended) A kit for the prevention or control of coccidiosis comprising,

a composition containing, sterile, viable, non-attenuated sporulated cocysts of at least one species of protozoa known to cause coccidiosis, said composition containing less than about 0.8% by weight of alkali metal dichromate the composition of claim 1; and

instructions for administration of said composition to an animal.

- 114. (original) A kit as set forth in claim 113 containing less than about 0.3% by weight of dichromate ion.
- 115. (original) A kit as set forth in claim 113 containing less than about 0.15% by weight of hexavalent chromium.
- 116. (previously presented) A kit as set forth in claim 113 wherein said composition is substantially free of alkali metal dichromate.
  - 117. (cancelled).
  - 118. (previously presented) A kit as set forth in claim 113, further comprising: a diluent, wherein said diluent is substantially free of alkali metal dichromate; and instructions for mixing said diluent with said composition to form a mixture.
- 119. (original) A kit according to claim 118, wherein said diluent comprises a sterile diluent.

Claims 120-135. (cancelled).

136. (currently amended) A composition as set forth in claim 1 for the prevention er control of coccidiosis comprising viable non-attenuated sporulated oocysts of at least one species of protozoa known to cause coccidiosis, said composition having been made by:

introducing into an aqueous sporulation medium occysts of at least one species of protozoa known to cause coccidiosis;

incubating said oocysts in said aqueous sporulation medium, thereby causing sporulation of oocysts; and

introducing an oxidizing agent into said medium so that the average dissolved oxygen content during sporulation is maintained at at least 30% of saturation; wherein said composition is substantially free of alkali metal dichromate.

- 137. (currently amended) A composition as set forth in claim 136 wherein said composition comprises viable non-attenuated sporulated oocysts from a species of *Eimeria* selected from the group consisting of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella*.
- 138. (currently amended) A composition as set forth in claim 137 wherein said composition comprises viable non-attenuated sporulated oocysts of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella*.
- 139. (currently amended) A composition as set forth in claim 137 wherein said composition comprises viable non-attenuated sporulated oocysts of *Eimeria acervulina*, *Eimeria maxima*, and *Eimeria tenella* in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations.
- 140. (currently amended) A composition as set forth in claim 137 wherein said composition comprises at least about 1.25 x 10 <sup>4</sup> viable <del>non-attenuated</del> sporulated oocysts per milliliter.
- 141. (previously presented) The composition as set forth in claim 137 wherein said composition is substantially free of added bactericide.
- 142. (original) A composition as set forth in claim 137 comprising a composition which ameliorates a decrease in post-challenge performance.

- 143. (original) A composition as set forth in claim 142 wherein said composition comprises *Proprionibacterium acnes*.
  - 144. (withdrawn) A composition comprising: viable, sporulated oocysts of at least one species of coccidial protozoa; and an anti-foaming agent.
- 145. (withdrawn) A composition as set forth in claim 144 wherein said antifoaming agent is Antifoam A.
- 146. (currently amended) A composition <u>as set forth in claim 1</u> for the prevention or control of coccidiosis comprising:

viable, sporulated occysts of at least one species of protozoa known to cause eccidiosis:

wherein said oocysts have been separated by tangential flow filtration from wherein said aqueous process medium is an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts can not enter the pores, but bacteria can pass through the pores.

- 147. (cancelled).
- 148. (currently amended) A composition for the prevention and treatment of coccidiosis as set forth in claim 1 further comprising:

a pharmaceutically acceptable carrier, diluent, or excipient; and viable, non-attenuated; sporulated oocysts of at least one species of protozoa known to cause coccidiosis:

wherein the sporulated oocysts are sterile, and said composition is substantially free of potassium dichromate.

- 149. (previously presented) The composition of claim 146 wherein the pore size is approximately 5 microns or greater.
- 150. (previously presented) The composition of claim 149 wherein the pore size is approximately 10 microns.
  - 151. (cancelled).
  - 152. (cancelled).
- 153. (new) The composition of claim 1 wherein the pore size is approximately 5 microns or greater.
- 154. (new) The composition of claim 1 wherein the pore size is approximately 10 microns.

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